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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,099	09/17/2003	Jennifer Maw	PD-267.00 (M190.151.101)	3704
7590 09/22/2006			EXAMINER	
Curtis D. Kinghorn Medtronic, Inc. 710 Medtronic Parkway N.E. Minneapolis, MN 55432			NGUYEN, TUAN VAN	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/664,099

Applicant(s)

MAW, JENNIFER

Examiner

Tuan V. Nguyen

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on January 9, 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17, drawn to a sealant dispensing device, classified in class 606, subclass 214.
 - II. Claims 34-36, drawn to method of applying sealant to the ear, drawn to class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus such as a syringe.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. A telephone call was made to Mr. Trevor Arnold (Reg. No. 51,416) on September 5, 2006 to discuss the above restriction requirement. The result was a provisional election was made without traverse to prosecute the invention of Group I, claims 1-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-19 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1-9, 10, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dragan (U.S. 4,569,662).**
5. Referring to claims 1-9, 11, and 12, Dragan discloses (see Figs. 1 and 5-7; col. 4, lines 20 to col.5, line 53; and col. 6, lines 31-62)) a system for delivering or dispensing a variety of different dental materials, thus the system is capable of deliver or dispense adhesive to an ear, comprising: a body or dental syringe 20; a handle 22, 23 having a terminus; a trigger 29 pivotally connected to handle 22, 23 through a joint at 24, 24A, and 30 which allows the trigger to pivot about the joint

when the trigger is squeezed; a reservoir assembly 61, which can be glass (see col. 7, lines 35-37), having a second end 61B and a first end includes thread 27 for attachment of the reservoir to the body 20; a dispensing mechanism operatively connected at one end to the trigger and at the other end to the reservoir; the dispensing mechanism includes plunger rod 34 having teeth 40 engaged with pawl 41 mounted on the trigger 29 (see col. 5, lines 35-40) and plunger tip 66 (see Fig. 5), wherein the outer diameter of plunger tip is approximately equal to the inner diameter of the reservoir (see col. 6, lines 54-60); a catheter or cannula 74 fluidly connected to the second end of the reservoir assembly 61 by threading or screw fitting 71B (see Fig. 6 and col. 7, lines 30-35).

6. Referring to **claim 10**, Dragan discloses (see Fig. 9) the cannula or tip 102, 102A is permanently affixed to the reservoir 100 by molding process (see col. 9, lines 15-25).
7. Referring to **claim 15**, Dragan discloses (see Fig. 9) the reservoir 100 contains light settable dental material (see col. 9, lines 25-40). Here it is noted that it is old and well known in the art that light settable dental materials for dental application has function equivalent to glue or adhesive.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 3731

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. **Claims 13, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan in view of Silverman et al. (U.S. 6,575,896).**
11. Referring to claims **13 and 14**, Dragan discloses the invention substantially as claimed except for a specific size of the needle gauge. Silverman discloses an apparatus and method of injecting a nonbiodegradable such as cyanoacrylate, which is a non-toxic chemical inert prepolymer for in situ (see col. 11, line 48-59) through a needle having a gauge size ranging from 16 to 28 preferably ranging from 23 to 26 gauge (see col. 4, lines 15-23) for treating of Gastroesophageal reflux disease. Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the applicant to use needle having gauge size ranging 10 to 26 for delivery of cyanoacrylate, as disclosed by Silverman, to incorporate into the device, as disclosed by Dragan because Applicant has not disclosed that the needle size ranging from 10 to 50

Art Unit: 3731

gauge provides an advantage, or solves a stated problem. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use needle having size ranging from 10 to 50 gauge, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

12. Referring to **claim 16**, Dragan discloses the invention substantially as claimed except for the material is cyanoacrylate adhesive. Silverman discloses an apparatus and method of injecting a nonbiodegradable such as cyanoacrylate, which is a non-toxic chemical inert prepolymer for in situ (see col. 11, line 48-59) for treating of Gastroesophageal reflux disease. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use cyanoacrylate, as disclosed by Silverman, to incorporate into the device, as disclosed by Dragan to gain the advantage of cyanoacrylate is a non-toxic and chemical inert.
13. **Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan in view of Wirt et al. (U.S. 6,648,852).**
14. Referring to **claim 17**, Dragan discloses the invention substantially as claimed except for the adhesive is a fibrin-base adhesive. However, Wirt discloses that fibrin-base adhesive for bond and or seal tissue is old and well known in the art (see col. 1, lines 28-38). Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the

Art Unit: 3731

applicant to use fibrin-base adhesive as disclosed by Wirt et al. because Applicant has not disclosed that the fibrin-base adhesive provides an advantage, or solves a stated problem.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
September 9, 2006




ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

9/15/06